

Arnold B. Calmann (abc@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

SAIBER LLC

One Gateway Center, 10th Floor

Newark, New Jersey 07102-5311

T: (973) 622-3333

F: (973) 622-3349

William A. Rakoczy (wrakoczky@rmmslegal.com)

Paul J. Molino (paul@rmmslegal.com)

John D. Polivick (jpolivick@rmmslegal.com)

Roy Chamcharas (rchamcharas@rmmslegal.com)

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 West Hubbard Street, Suite 500

Chicago, IL 60654

T: (312) 527-2157

F: (312) 527-4205

Attorneys for Defendants

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

SCHERING CORPORATION,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

Civil Action No. 09-6373 (GEB) (TJB)

**DEFENDANTS APOTEX INC. AND
APOTEX CORP.'S ANSWER TO
COMPLAINT, SEPARATE DEFENSES,
COUNTERCLAIMS AND DEMAND FOR
JURY TRIAL**

DOCUMENT FILED ELECTRONICALLY

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") hereby answer the Complaint – for which every allegation not expressly admitted is denied – as follows:

ALLEGED PARTIES

1. Schering Corporation ("Schering") is a New Jersey corporation with its principal place of business at 3070 US Highway 22, Branchburg, New Jersey 08876.

ANSWER: Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1, and therefore denies these allegations.

2. On information and belief, Defendant Apotex Inc. (“Apotex”) is a Canadian company with offices at 150 Signet Drive, Toronto, Canada M9L 1T9.

ANSWER: Apotex admits that Apotex Inc. is a corporation existing solely under the laws of Canada, having its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada. Apotex denies all remaining allegations of Paragraph 2.

3. On information and belief, Defendant Apotex Corp. (“Apotex USA”) regularly transacts business in New Jersey and is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Apotex admits that Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex denies that Apotex Corp. is a proper party to this suit, and also denies that the Court has subject matter jurisdiction for any claims asserted against Apotex Corp. Apotex denies all remaining allegations of Paragraph 3.

4. On information and belief, Apotex USA is the United States subsidiary of Apotex.

ANSWER: Apotex denies the allegations of Paragraph 4.

5. On information and belief, Apotex conducts business operations in the United States, including in the State of New Jersey, through Apotex USA.

ANSWER: Apotex denies the allegations of Paragraph 5.

ALLEGED JURISDICTION AND VENUE

6. This action arises under the Patent Statute of the United States of America, Title 35, United States Code, and jurisdiction is founded on Title 28, United States Code §§ 1331 and 1338(a).

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that this action purports to arise

under the patent laws, and that subject matter jurisdiction is proper solely for the claims directed against Apotex Inc. only. Apotex denies that Apotex Corp. is a proper party to this suit, and further denies that subject matter jurisdiction is proper for any claims asserted against Apotex Corp. Apotex denies all remaining allegations of Paragraph 6.

7. This Court has personal jurisdiction over Apotex because Apotex has maintained continuous and systematic contacts with the State of New Jersey.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial District solely for purposes of this action only. Apotex denies all remaining allegations of Paragraph 7.

8. Apotex has previously submitted to the jurisdiction of this Court in several cases and has previously availed itself of the District of New Jersey by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Apotex denies the allegations of Paragraph 8.

9. On information and belief, generic drug products developed and manufactured by Apotex and approved by the FDA are for sale and are sold in the State of New Jersey.

ANSWER: Apotex denies the allegations of Paragraph 9.

10. This Court has personal jurisdiction over Apotex USA because Apotex USA has maintained continuous and systematic contacts with the State of New Jersey.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial District solely for purposes of this action only. Apotex denies that Apotex Corp. is a proper party to this suit, and further denies that subject matter jurisdiction is proper for any claims asserted against Apotex Corp. Apotex denies the remaining allegations of Paragraph 10.

11. Apotex USA has previously submitted to the jurisdiction of this Court in several cases and has previously availed itself of the District of New Jersey by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

ANSWER: Apotex denies the allegations of Paragraph 11.

12. On information and belief, Apotex USA markets and sells drug products in the United States manufactured by Apotex, following any FDA approval. Apotex USA markets and sells such drugs products in this judicial District and has registered as a wholesaler with the New Jersey Department of Health and Senior Services.

ANSWER: Apotex denies the allegations of Paragraph 12.

13. Apotex USA's acts and continuous contacts with the State of New Jersey, as an agent for Apotex, are also attributable to Apotex for jurisdictional purposes.

ANSWER: Apotex denies the allegations of Paragraph 13.

14. For all the reasons set forth above, this Court has personal jurisdiction over Apotex and Apotex USA.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this judicial District solely for purposes of this action only. Apotex denies all remaining allegations of Paragraph 14.

15. Venue is proper in this Court for this action under at least Title 29, United States Code § 1391(b) and (c).

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Apotex does not contest venue for purposes of this action only. Apotex denies all remaining allegations of Paragraph 15.

ALLEGED BACKGROUND

16. On November 17, 1998, United States Letters Patent No. 5,837,699 (the '699 patent), entitled USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES, duly and legally issued to Joel A. Sequeira, Francis M. Cuss, Keith B.

Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen. The ‘699 patent is currently scheduled to expire on January 27, 2014. The ‘699 patent discloses and claims novel pharmaceutical compositions of mometasone furoate, as well as novel methods for treating diseases of the upper airway passages, including allergic or nonallergic rhinitis, with these compositions. A copy of the ‘699 patent is attached to this Complaint as Exhibit 1.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that, according to the electronic records of the United States Patent and Trademark Office (“PTO”), the PTO issued U.S. Patent No. 5,837,699 (“the ‘699 patent”), titled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” on or about November 17, 1998, to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen, and that what purports to be a copy of the ‘699 patent is attached to the Complaint as Exhibit 1. Apotex denies that the ‘699 patent was “duly and legally issued,” and further denies all remaining allegations of Paragraph 16.

17. On October 3, 2000, United States Letters Patent No. 6,127,353 (the ‘353 patent), entitled MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS, duly and legally issued to Pui-Ho Yen, Charles Eckhart, Teresa Etlinger, and Nancy Levine. The ‘353 patent is currently scheduled to expire on October 3, 2017. The ‘353 patent discloses and claims novel form(s) of mometasone furoate monohydrate (also designated $9\alpha,21$ -dichloro- 16α -methyl- $1,4$ -pregnadiene- $11\beta,17\alpha$ -diol- $3,20$ -dione- 17 -($2'$ -furoate) monohydrate) and novel pharmaceutical compositions thereof. A copy of the ‘353 patent is attached to this Complaint as Exhibit 2.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that, according to the electronic records of the PTO, the PTO issued U.S. Patent No. 6,127,353 (“the ‘353 patent”), titled “MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS,” on or about October 3, 2000, to Pui-Ho Yuen, Charles Eckhart, Teresa Etlinger, and Nancy Levine, and that what purports to be a copy of the

‘353 patent is attached to the Complaint as Exhibit 2. Apotex denies that the ‘353 patent was “duly and legally issued,” and further denies all remaining allegations of Paragraph 17.

18. On April 20, 2004, United States Letters Patent No. 6,723,713 (the ‘713 patent), entitled USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES, duly and legally issued to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen. The ‘713 patent is currently scheduled to expire on January 27, 2014. The ‘713 patent discloses and claims novel pharmaceutical compositions of mometasone furoate, as well as novel methods for treating diseases of the upper airway passages, including allergic rhinitis, with these compositions. A copy of the ‘713 patent is attached to this Complaint as Exhibit 3.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that, according to the electronic records of the PTO, the PTO issued U.S. Patent No. 6,723,713 (“the ‘713 patent”), titled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” on or about April 20, 2004, to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen, and that what purports to be a copy of the ‘713 patent is attached to the Complaint as Exhibit 3. Apotex denies that the ‘713 patent was “duly and legally issued,” and further denies all remaining allegations of Paragraph 18.

19. Schering is the owner through assignment of the ‘699, ‘353, and ‘713 patents, and Schering-Plough Corporation is the owner of an approved New Drug Application for mometasone furoate monohydrate metered nasal spray (NDA No. 20-762) that is sold under the trademark Nasonex®.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the cover pages of the ‘699, ‘353, and ‘713 patents identify “Schering Corporation” as the purported assignee. Further answering, Apotex admits that the electronic version of the Food and Drug Administration’s (“FDA”) publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”), identifies “SCHERING PLOUGH” as

the applicant for New Drug Application (“NDA”) No. 20-762 for Nasonex®. Apotex denies all remaining allegations of Paragraph 19.

20. Schering's Nasonex® nasal spray is extremely successful and is widely used in New Jersey, the United States, and throughout the world to treat diseases of the upper airways, including allergic and nonallergic rhinitis.

ANSWER: Apotex denies the allegations of Paragraph 20.

21. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) identifies drug products approved on the basis of safety and effectiveness by the United States Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA). Schering has listed the ‘699, ‘353, and ‘713 patents in the Orange Book as covering its Nasonex® nasal spray.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that the electronic version of the Orange Book lists the ‘699, ‘353, and ‘713 patents in connection with Nasonex®. Apotex denies all remaining allegations of Paragraph 21.

22. On information and belief, Apotex has filed an Abbreviated New Drug Application with the FDA for generic mometasone furoate nasal spray, 50 mcg (ANDA No. 91-161). Apotex’s ANDA No. 91-161 allegedly contains a certification under Title 21, United States Code § 355(j)(2)(A)(vii)(IV) and Title 21, Code of Federal Regulations, § 314.95, that each of the ‘699, ‘353, and ‘713 patents are “invalid, unenforceable, or will not be infringed.” Notice of that certification, but not the certification, was transmitted to Schering and Schering-Plough Corporation on or after November 6, 2009, and received by Schering on or after November 9, 2009.

ANSWER: Apotex admits that Apotex Inc. has filed an Abbreviated New Drug Application (“ANDA”) with FDA for Mometasone Furoate Nasal Spray, 50 mcg; that Apotex Inc.’s ANDA contains a “paragraph IV certification” stating that, in Apotex Inc.’s opinion and to the best of its knowledge, each of the ‘699, ‘353, and ‘713 patents is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Apotex Inc.’s ANDA; and that Apotex Inc. provided the requisite notice of its

ANDA to Schering and Schering-Plough Corporation, among others. Apotex denies all remaining allegations of Paragraph 22.

23. Apotex has refused to make ANDA No. 91-161 or samples of its proposed generic copy of Nasonex® nasal spray available to Schering under reasonable conditions that would allow evaluation before the filing this Complaint.

ANSWER: Apotex denies the allegations of Paragraph 23.

24. Upon information and belief, Apotex's proposed generic copy would contain mometasone furoate in such a form that would infringe the '353 patent.

ANSWER: Apotex denies the allegations of Paragraph 24.

25. Upon information and belief, Apotex's proposed generic copy represents a composition that is intended to be used in a manner that would infringe the '699 and '713 patents.

ANSWER: Apotex denies the allegations of Paragraph 25.

26. On information and belief, Apotex filed ANDA No. 91-161 because both Apotex and its U.S. subsidiary, Apotex USA, seek to enter the lucrative intranasal mometasone furoate market that Nasonex® nasal spray has created with its beneficial and advantageous treatments for diseases of the upper airways, including allergic and nonallergic rhinitis.

ANSWER: Apotex denies the allegations of Paragraph 26.

27. On information and belief, Apotex USA actively and knowingly aided and abetted Apotex's filing of ANDA No. 91-161 and would be involved in any manufacturing, marketing, sale, and/or distribution of Apotex's proposed generic copies of Nasonex® nasal spray in the United States.

ANSWER: Apotex denies the allegations of Paragraph 27.

AS TO THE ALLEGATIONS IN COUNT I

28. Each of the preceding paragraphs 1 – 27 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 as though fully set forth herein.

29. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '699 patent, before the expiration of the '699 patent. On

information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Apotex denies the allegations of Paragraph 29.

30. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '699 patent, Apotex was aware of the existence of the '699 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

ANSWER: Apotex denies the allegations of Paragraph 30.

31. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '699 patent.

ANSWER: Apotex denies the allegations of Paragraph 31.

AS TO THE ALLEGATIONS IN COUNT II

32. Each of the preceding paragraphs 1 – 27 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 as though fully set forth herein.

33. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA No. 91-161, Apotex USA was aware of the '699 patent and knew that Apotex's filing of ANDA No. 91-161 constituted an act of infringement.

ANSWER: Apotex denies the allegations of Paragraph 33.

34. On information and belief, Apotex USA has committed an act of infringement under 35 U.S.C. § 271(b).

ANSWER: Apotex denies the allegations of Paragraph 34. Further answering, Apotex denies that the Court has subject matter jurisdiction over claims asserted under 35 U.S.C. § 271(b).

35. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '699 patent.

ANSWER: Apotex denies the allegations of Paragraph 35.

AS TO THE ALLEGATIONS IN COUNT III

36. Each of the preceding paragraphs 1 – 27 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 as though fully set forth herein.

37. On information and belief, Apotex filed ANDA No. 91-161 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product which is claimed in the ‘353 patent, before the expiration of the ‘353 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Apotex denies the allegations of Paragraph 37.

38. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the ‘353 patent, Apotex was aware of the existence of the ‘353 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

ANSWER: Apotex denies the allegations of Paragraph 38.

39. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the ‘353 patent.

ANSWER: Apotex denies the allegations of Paragraph 39.

AS TO THE ALLEGATIONS IN COUNT IV

40. Each of the preceding paragraphs 1 – 27 and 32 – 35 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 and 32 through 35 as though fully set forth herein.

41. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA 91-161, Apotex USA was aware of the ‘353 patent and knew that Apotex's filing of ANDA No. 91-161 constituted an act of infringement.

ANSWER: Apotex denies the allegations of Paragraph 41.

42. On information and belief, Apotex USA has committed an act of infringement under 35 U.S.C. § 271(b).

ANSWER: Apotex denies the allegations of Paragraph 42. Further answering, Apotex denies that the Court has subject matter jurisdiction over claims asserted under 35 U.S.C. § 271(b).

43. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '353 patent.

ANSWER: Apotex denies the allegations of Paragraph 43.

AS TO THE ALLEGATIONS IN COUNT V

44. Each of the preceding paragraphs 1 – 27 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 as though fully set forth herein.

45. On information and belief, Apotex filed ANDA 91-161 to obtain approval under the FFDCA to engage in the commercial manufacture, use, or sale of a drug product the use of which is claimed in the '713 patent, before the expiration of the '713 patent. On information and belief, Apotex has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Apotex denies the allegations of Paragraph 45.

46. On information and belief, when Apotex filed ANDA No. 91-161 seeking approval to market generic mometasone furoate nasal spray before the expiration of the '713 patent, Apotex was aware of the existence of the '713 patent and that the filing of ANDA No. 91-161 constituted an act of infringement of that patent.

ANSWER: Apotex denies the allegations of Paragraph 46.

47. On information and belief, Apotex acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '713 patent.

ANSWER: Apotex denies the allegations of Paragraph 47.

AS TO THE ALLEGATIONS IN COUNT VI

48. Each of the preceding paragraphs 1 – 27 and 40 – 43 is incorporated as if fully set forth herein.

ANSWER: Apotex restates and incorporates by reference its responses to the allegations of Paragraphs 1 through 27 and 40 through 43 as though fully set forth herein.

49. On information and belief, when Apotex USA actively and knowingly aided and abetted Apotex with its drafting and/or filing of ANDA No. 91-161, Apotex USA was aware of the '713 patent and knew that Apotex's filing of ANDA No. 91-161 constituted an act of infringement.

ANSWER: Apotex denies the allegations of Paragraph 49.

50. On information and belief, Apotex USA has committed an act of infringement under 35 U.S.C. § 271(b).

ANSWER: Apotex denies the allegations of Paragraph 50. Further answering, Apotex denies that the Court has subject matter jurisdiction over claims asserted under 35 U.S.C. § 271(b).

51. On information and belief, Apotex USA acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '713 patent.

ANSWER: Apotex denies the allegations of Paragraph 51.

* * *

Apotex denies all allegations and statements not expressly admitted or responded to herein. Apotex further denies that Schering is entitled to any of the relief requested, or to any relief at all.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting any allegation or statement in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Apotex asserts the following separate defenses:

First Separate Defense

The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and will not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of United States Patent No.

5,837,699 (“the ‘699 patent”), United States Patent No. 6,127,353 (“the ‘353 patent”), or United States Patent No. 6,723,713 (“the ‘713 patent”), either literally or under the doctrine of equivalents.

Second Separate Defense

Apotex has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ‘699, ‘353, or ‘713 patents.

Third Separate Defense

Apotex has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ‘699, ‘353, or ‘713 patents.

Fourth Separate Defense

The claims of the ‘699, ‘353, and ‘713 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for obviousness-type double patenting.

Fifth Separate Defense

The Court lacks subject matter jurisdiction over any declaratory judgment claims and/or claims asserted under 35 U.S.C. §§ 271(a), (b), and/or (c).

Sixth Separate Defense

The Court lacks subject matter jurisdiction because there is no case or controversy as to invalid and/or unenforceable patent claims.

Seventh Separate Defense

The Court lacks subject matter jurisdiction over any and all claims directed toward Apotex Corp.

Eighth Separate Defense

Apotex Corp. is not a proper party to this suit.

Ninth Separate Defense

The Complaint fails to state a claim upon which relief can be granted.

Tenth Separate Defense

The Complaint fails to state a claim for willful infringement and/or exceptional case.

Eleventh Separate Defense

Any additional defenses or counterclaims that discovery may reveal.

* * *

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. (collectively “Apotex”) assert the following counterclaims against Plaintiff/Counterclaim-Defendant Schering Corporation (“Schering”).

Parties

1. Apotex Inc. is a corporation existing solely under the laws of Canada, having its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada.

2. Apotex Corp. is a Delaware corporation, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. On information and belief, Schering Corporation purports to be a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 3070 US Highway 22, Branchburg, New Jersey 08876.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Schering because Schering has availed itself of the rights and privileges of this forum by suing Apotex in this District, and because Schering conducts substantial business in, and has regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

Patents-in-Suit

8. On or about November 17, 1998, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 5,837,699 (“the ‘699 patent”), entitled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A. Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen.

9. On or about October 3, 2000, the PTO issued U.S. Patent No. 6,127,353 (“the ‘353 patent”), entitled “MOMETASONE FUROATE MONOHYDRATE, PROCESS FOR MAKING SAME AND PHARMACEUTICAL COMPOSITIONS,” to Pui-Ho Yuen, Charles Eckhart, Teresa Etlinger, and Nancy Levine.

10. On or about April 20, 2004, the PTO issued U.S. Patent No. 6,723,713 (“the ‘713 patent”), entitled “USE OF MOMETASONE FUROATE FOR TREATING UPPER AIRWAY PASSAGE DISEASES,” to Joel A. Sequeira, Francis M. Cuss, Keith B. Nolop, Imtiaz A.

Chaudry, Nagamani Nagabhushan, James E. Patrick, and Mitchell Cayen.

11. Schering purports and claims to own the ‘699, ‘353, and ‘713 patents.

12. On or about December 18, 2009, Schering sued Apotex in this District alleging infringement of the ‘699, ‘353, and ‘713 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the ‘699 Patent)

13. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

14. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘699 patent, either directly or indirectly.

15. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.’s ANDA stent has infringed, does infringe, or would infringe the ‘699 patent.

16. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex’s non-infringement of the ‘699 patent.

17. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘699 patent, either directly or indirectly.

COUNT II
(Declaratory Judgment of Invalidity of the ‘699 Patent)

18. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

19. The claims of the ‘699 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

20. Schering maintains – and Apotex denies – that the claims of the ‘699 patent are valid.

21. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the ‘699 patent.

22. Apotex is entitled to a judicial declaration that the claims of the ‘699 patent are invalid.

COUNT III
(Declaratory Judgment of Non-Infringement of the ‘353 Patent)

23. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

24. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘353 patent, either directly or indirectly.

25. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.’s ANDA stent has infringed, does infringe, or would infringe the ‘353 patent.

26. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex's non-infringement of the '353 patent.

27. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '353 patent, either directly or indirectly.

COUNT IV
(Declaratory Judgment of Invalidity of the '353 Patent)

28. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

29. The claims of the '353 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

30. Schering maintains – and Apotex denies – that the claims of the '353 patent are valid.

31. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '353 patent.

32. Apotex is entitled to a judicial declaration that the claims of the '353 patent are invalid.

COUNT V
(Declaratory Judgment of Non-Infringement of the '713 Patent)

33. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

34. The manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '713 patent, either directly or indirectly.

35. Schering maintains – and Apotex denies – that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has infringed, does infringe, or would infringe the '713 patent.

36. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Apotex's non-infringement of the '713 patent.

37. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '713 patent, either directly or indirectly.

COUNT VI
(Declaratory Judgment of Invalidity of the '713 Patent)

38. Apotex re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

39. The claims of the '713 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for obviousness-type double patenting.

40. Schering maintains – and Apotex denies – that the claims of the '713 patent are

valid.

41. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Schering having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the '713 patent.

42. Apotex is entitled to a judicial declaration that the claims of the '713 patent are invalid.

DEMAND FOR JURY TRIAL

Defendants/Counterclaim-Plaintiffs demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Apotex Inc. and Apotex Corp. respectfully pray for judgment in their favor and against Schering Corporation:

- a. Declaring that the manufacture, use, sale, offer for sale, or importation of the Mometasone Furoate Nasal Spray, 50 mcg, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '699, '353, or '713 patents, either directly or indirectly;
- b. Declaring the claims of the '699, '353, and '713 patents invalid;
- c. Ordering that Schering's Complaint be dismissed with prejudice and judgment entered in favor of Apotex;
- d. Declaring this case exceptional and awarding Apotex reasonable attorneys' fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

- e. Awarding Apotex such other and further relief as the Court may deem just and proper.

Respectfully submitted,

SAIBER LLC

Attorneys for Defendants

Dated: February 9, 2010

By: s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

One Gateway Center, 10th Floor

Newark, New Jersey 07102-5311

T: (973) 622-3333

F: (973) 622-3349

William A. Rakoczy

(wrakoczky@rmmslegal.com)

Paul J. Molino

(paul@rmmslegal.com)

John D. Polivick

(jpolivick@rmmslegal.com)

Roy Chamcharas

(rchamcharas@rmmslegal.com)

RAKOCZY MOLINO MAZZOCHI

SIWIK LLP

6 West Hubbard Street, Suite 500

Chicago, IL 60654

T: (312) 527-2157

F: (312) 527-4205

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Apotex Inc. and Apotex Corp., by their undersigned counsel, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is not the subject of any other action asserted by Defendants in any court, or of any pending arbitration or administrative proceeding.

Dated: February 9, 2010

SAIBER LLC

Attorneys for Defendants

Apotex Inc. and Apotex Corp.

/s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

One Gateway Center, 10th Floor

Newark, NJ 07102-5311

Telephone: (973) 622-3333

Facsimile: (973) 622-3349

William A. Rakoczy (wrakoczky@rmmslegal.com)

Paul J. Molino (paul@rmmslegal.com)

John D. Polivick (jpolivick@rmmslegal.com)

Roy Chamcharas (rchamcharas@rmmslegal.com)

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 West Hubbard Street, Suite 500

Chicago, IL 60654

Telephone: (312) 527-2157

Facsimile: (312) 527-4205

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Under Local Civil Rule 201.1, Apotex Inc. and Apotex Corp., by their undersigned counsel, hereby certify that, in addition to monetary relief greater than \$150,000, the parties seek injunctive and declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: February 9, 2010

SAIBER LLC

Attorneys for Defendants

Apotex Inc. and Apotex Corp.

/s/ Arnold B. Calmann

Arnold B. Calmann (abc@saiber.com)

Jakob B. Halpern (jbh@saiber.com)

One Gateway Center, 10th Floor

Newark, NJ 07102-5311

Telephone: (973) 622-3333

Facsimile: (973) 622-3349

William A. Rakoczy (wrakoczky@rmmslegal.com)

Paul J. Molino (paul@rmmslegal.com)

John D. Polivick (jpolivick@rmmslegal.com)

Roy Chamcharas (rchamcharas@rmmslegal.com)

RAKOCZY MOLINO MAZZOCHI SIWIK LLP

6 West Hubbard Street, Suite 500

Chicago, IL 60654

Telephone: (312) 527-2157

Facsimile: (312) 527-4205